

WHAT IS CLAIMED IS:

1. A pharmaceutical composition comprising a pharmacologically effective amount of a poorly soluble drug and a solubilizing compound selected from the group consisting of hydrotropic agent monomers, hydrotropic polymers, and hydrotropic hydrogels, wherein the solubilizing compound includes at least one hydrophobic moiety.
- 5 2. The composition of claim 1; wherein the solubilizing compound is a hydrotropic polymer or hydrotropic hydrogel.
3. The composition of claim 1, wherein the hydrophobic moiety is selected from the group consisting of substituted and unsubstituted aryl groups, substituted and 10 unsubstituted nitrogen heterocycles, alkyl groups, alkylene groups, aralkyl groups, and methacryloyl groups.
- 10 4. The composition of claim 1, wherein the hydrophobic moiety is a substituted or unsubstituted pyridyl group.
- 5 5. The composition of claim 1, wherein the hydrophobic moiety is selected from the group consisting of N,N-diethylnicotinamide, N-picolylnicotinamide, N-allylnicotinamide, sodium salicylate, 2-methacryloyloxyethyl phosphorylcholine, resorcinol, N,N-dimethylnicotinamide, N-methylnicotinamide, butylurea, pyrogallol, 3-picollyacetamide, procaine HCl, nicotinamide, pyridine, 3-picollyamine, sodium ibuprofen, sodium xylenesulfonate, and ethyl carbamate.
- 20 6. The composition of claim 1, wherein the poorly soluble drug has a solubility in water of less than about 100 µg/ml at 37°C.
7. The composition of claim 1, wherein the poorly soluble drug is selected from the group consisting of paclitaxel, griseofulvin, progesterone, and tamoxifen.
- 25 8. A hydrotropic polymer or copolymer capable of increasing water solubility of a poorly soluble drug, wherein the polymer or copolymer comprises at least one hydrotropic agent monomer unit that includes a hydrophobic moiety.
9. The polymer or copolymer of claim 8, wherein the hydrophobic moiety is selected 30 from the group consisting of substituted and unsubstituted aryl groups, substituted and unsubstituted nitrogen heterocycles, alkyl groups, alkylene groups, aralkyl groups, and methacryloyl groups.

10. The polymer or copolymer of claim 8, which has a block, graft, alternating or random arrangement of monomer units.
11. The polymer or copolymer of claim 8, which has an acrylate or methacrylate backbone.
- 5 12. The polymer or copolymer of claim 8, which contains a spacer group.
13. The polymer of claim 8, which is a homopolymer of a hydrotropic agent monomer.
14. The polymer or copolymer of claim 8, wherein the hydrotropic agent monomer unit is selected from the group consisting of polymerizable derivatives of nicotinamide, N-substituted nicotinamide, pyridinium, N-substituted pyridinium, benzyl, urea, thiourea, pyridone, pyrimidone, melamine, pyridine, pyrazine, nicotine, triazine, salicylamide, salicylic acid, and sulfimide.
- 10 15. The polymer or copolymer of claim 8, wherein the at least one hydrotropic agent monomer unit is selected from the group consisting of vinyl derivatives of ibuprofen, nicotinamide, salicylic acid, N-picolylnicotinamide, salicylaldehyde, N,N'-dimethylnicotinamide, N,N'-diethylnicotinamide, and pyridine.
16. The polymer or copolymer of claim 8, wherein the poorly soluble drug has a solubility in water of less than about 100 µg/ml at 37°C.
- 15 17. The polymer or copolymer of claim 16, wherein the poorly soluble drug is paclitaxel, griseofulvin, progesterone, or tamoxifen.
- 20 18. A hydrotropic hydrogel capable of increasing water solubility of a poorly soluble drug, wherein the hydrogel is formed by polymerizing at least one hydrotropic agent monomer in the presence of a crosslinking agent.
19. The hydrogel of claim 18, wherein the poorly soluble drug has a solubility in water of less than about 100 µg/ml at 37°C.
- 25 20. The hydrogel of claim 18, which is capable of increasing the solubility of paclitaxel.
21. A method of increasing water solubility of a hydrophobic compound comprising combining the hydrophobic compound with a solubilizing compound selected from the group consisting of hydrotropic agents, hydrotropic agent monomers, hydrotropic polymers, and hydrotropic hydrogels, wherein the solubilizing compound includes a hydrophobic moiety.

22. A method of administering a poorly soluble drug to a patient comprising
administering to the patient a composition containing the drug and a solubilizing
compound selected from the group consisting of hydrotropic agents, hydrotropic
agent monomers, hydrotropic polymers, and hydrotropic hydrogels, wherein the
solubilizing compound includes a hydrophobic moiety.
- 5 23. The method of claim 22, wherein the composition is administered orally.
24. The method of claim 22, wherein the poorly soluble drug has an aqueous solubility of
less than about 100 µg/ml at 37°C in the absence of said solubilizing compound.
25. A method of making a hydrotropic polymer comprising polymerizing at least one
10 hydrotropic agent monomer, wherein the monomer contains a hydrophobic moiety.
26. A method of making a hydrotropic polymer comprising grafting a hydrotropic agent
to a polyacrylate, polymethacrylate, polyacrylamide, polyol, or polyamine backbone.
27. A method of making a hydrotropic hydrogel comprising polymerizing at least one
15 hydrotropic agent monomer in the presence of a crosslinking agent.
28. A method of forming a solid dispersion of a poorly water-soluble drug and a
solubilizing agent selected from the group consisting of hydrotropic agents,
hydrotropic agent monomers, hydrotropic polymers, and hydrotropic hydrogels, said
solubilizing compound containing a hydrophobic moiety, comprising:
melting the drug in the presence of the solubilizing compound; and
allowing the resulting composition to cool.
- 20 29. A method of removing lipids from a lipid-containing extract comprising contacting
the extract with a solubilizing compound selected from the group consisting of
hydrotropic agents, hydrotropic agent monomers, hydrotropic polymers and
hydrotropic hydrogels.
- 25 30. A method of forming submicron sized particles of a poorly soluble drug comprising:
forming an admixture of the drug and a solubilizing compound selected from the
group consisting of hydrotropic agents, hydrotropic agent monomers, hydrotropic
polymers and hydrotropic hydrogels; and
diluting the admixture in water, thereby precipitating the drug particles.